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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,089	08/21/2003	David Ernest Hartley	PA-5340 -RFB	7302
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EXAMINER TOWA, REINE T				
ART UNIT 3736		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/645,089

Applicant(s)

HARTLEY ET AL.

Examiner

RENE TOWA

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 7-9, 11, 12, 14, 28 and 35-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 7-9, 11, 12, 14, 28 and 35-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 28, 2008 has been entered.
2. This Office action is responsive to an amendment filed March 28, 2008. Claims 1, 3-4, 7-9, 11-12, 14, 28 and 35-47 are pending. Claims 1, 3-4, 36, 40 & 41 have been amended. Claims 2, 5-6, 10, 13, 15-27 and 29-34 have been cancelled.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. **Claims 1, 3-4, 8-9, 12, 14, 36-37 & 40-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (US 5,421, 349) in view of Radisch, Jr. (US 5,295,493), Stevens et al. (US 5,584,803), and further in view of Chaisson et al. (US 6,086,548).

In regards to **claims 1, 36 & 41**, Rodriguez et al. disclose a guide wire 10, the guide wire 10 having 5 zones of varying stiffness comprising:

a mandrel 11;

a proximal zone 22 of transition from high stiffness to semi-stiffness and having a length of about 3 cm;

an elongate central zone 11 of high stiffness and substantially constant diameter along its length;

a tapered distal zone 14 of transition from high stiffness to being relatively flexible and wherein the distal zone 14 is subdivided three zones:

a semi stiff zone adjacent to the central zone;

a transition zone having flexibility of from semi-stiff extending to flexible; and,

a tip zone having flexibility;

wherein the proximal zone 22 comprises a proximal wire coil 30 of substantially constant diameter and the distal zone 14 comprises a distal wire coil 18 of substantially constant diameter (see figs. 1-2; col. 2, lines 19-20, 27-31, 42-44 & 66-68; col. 3, lines 26-29 & 41-44; see claims 1 & 4 of Rodriguez).

In regards to **claim 4**, Rodriguez et al. disclose a guide wire 10 wherein the proximal zone 22 comprises a tapered mandrel with a proximal wire coil 30 of substantially constant coil diameter on and extending along the tapered mandrel (see fig. 2).

In regards to **claim 8**, Rodriguez et al. disclose a guide wire 10 wherein the proximal wire coil 30 terminates in a rounded tip 32 (see fig. 2; col. 3, lines 36-41).

In regards to **claim 9**, Rodriguez et al. disclose a guide wire 10 wherein the distal zone 14 comprises in order from the central zone 11, a tapered mandrel portion and a portion¹⁶ of constant reduced diameter with a distal wire coil 18 of substantially

constant coil diameter on and extending along the tapered mandrel portion and the portion 16 of constant reduced diameter (see fig. 1).

In regards to **claims 12 & 46**, Rodriguez et al. disclose a guide wire 10 wherein the distal wire coil 18 terminates in a rounded tip (see fig. 1).

In regards to **claim 37**, Rodriguez et al. disclose a guide wire 10 wherein the diameter of the mandrel in the central zone, the coil diameter of the proximal wire coil and the coil diameter of the distal wire coil are of substantially equal (see fig. 1).

In regards to **claim 44**, Rodriguez et al. disclose a guide wire 10 having a transition from full stiffness to semi-stiff at the proximal end, the semi-stiff proximal portion providing flexibility to allow the interventional delivery system to be loaded onto the wire 10 and advanced without becoming jammed in the interior of the device (see figs. 1-2).

Rodriguez et al. teach a guide wire, as described above, that fails to explicitly teach a distal zone having a distal pre-formed curve with a radius of curvature of from 5 cm to 15 cm or J-tip zone with a radius of curvature of from 5 to 20 mm.

However, **Radisch, Jr.** teaches that it is known to provide a guide wire with a distal zone having a distal pre-formed curve (22, 30, 40, 30a) with a radius such that the guide wire may correspond in shape to an arterial path through the aorta and into an artery of the heart such as a right coronary artery (RCA), a left anterior descending artery (LAD), a left circumflex artery (LCX), or a bypass graft in order to introduce an atherectomy cutter for removing a stenosis from the artery; wherein the central zone comprises a stainless steel mandrel (see abstract; see figs. 1-1A, 2-2A, 3-3A & 4-4A;

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col. 2, lines 52-68; col. 3, lines 1-6 & 24-28; col. 4, lines 15-22, 30-42 & 58-67; col. 5, lines 12-18 & 33-45).

Moreover, **Stevens et al.** teach that it is known to provide anatomical devices with a distal pre-formed U-shaped curve for insertion into a thoracic arch region of an aorta such that the distal curve defines a radius of curvature of about 5 cm to 8 cm (see fig. 36a; see col. 8, lines 59-67; col. 9, lines 1-10; col. 41, lines 66-67; col. 42, lines 1-10).

Even moreover, **Chaisson et al.** teach that it is known to provide anatomical devices for insertion into a thoracic arch region of an aorta with J-shaped distal tip having a radius of curvature of about 20 mm (see abstract; see figs. 5 & 9; col. 4, lines 35-37).

In regards to **claims 1, 14, 36 & 40-43**, since Radisch, Jr. teach that it is known to shape the distal zone of a guide wire to match an anatomical shape such that the guide wire may correspond in shape to an arterial path to hold the guide wire in its prepositioned place through the aorta and into an artery of the heart such as a right coronary artery (RCA), a left anterior descending artery (LAD), a left circumflex artery (LCX), or a bypass graft in order to introduce an atherectomy cutter for removing a stenosis from the artery (see col. 2, lines 52-68; col. 3, lines 24-28), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the guide wire of Rodriguez et al. to shape the distal zone into a pre-formed anatomical curve as taught by Radisch, Jr. so that the guide wire may correspond in shape to an arterial path to hold the guide wire in its prepositioned place through the

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aorta and into an artery of the heart such as a right coronary artery (RCA), a left anterior descending artery (LAD), a left circumflex artery (LCX), or a bypass graft in order to introduce an atherectomy cutter for removing a stenosis from the artery.

Moreover, both Radisch, Jr. and Stevens et al. teach anatomical devices having a distal pre-formed U-shaped curve for insertion into a thoracic arch region of an aorta to correspond to the curvature of a patient's aortic arch; since Stevens et al. further teach that it is known to provide said anatomical device with a radius of curvature of about 5 cm to 8 cm in order to position the distal end of the anatomical device in the ascending aorta when the anatomical device is disposed in the aortic arch (see col. 8, lines 59-67), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr. above to include a distal pre-formed curve with a radius of curvature of from 5 cm to 8 cm as taught by Stevens et al. in order to position the distal end of the anatomical device in the ascending aorta when the anatomical device is disposed in the aortic arch.

Even moreover, it is known to provide anatomical guide wires with J-shaped tip zone to reduce the likelihood of trauma caused by the advancing guide wire (see fig. 1 & col. 6, lines 35-44 of US 6,254,550). Since Rodriguez et al. teach that the distal end 14 may be curved (see fig. 1; see col. 3, lines 7-8) and Chaisson et al. teach it is known to provide anatomical devices for insertion into a thoracic arch region of an aorta with J-shaped distal tip having a radius of curvature of about 20 mm, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to

provide the guide wire of Rodriguez et al. as modified by Radisch, Jr. and Stevens et al., above, with a J-shaped tip zone having a radius of curvature of 20 mm as taught by Chaisson et al. in order to reduce the likelihood of trauma caused by the advancing guide wire.

In regards to **claim 3**, since Radisch, Jr. teaches that it is desirable to provide the the guide wire with a suitably strong material such as stainless so that the guide wire can be formed and maintained in the desired shape (see Radisch, Jr., col. 4, lines 18-22), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr. and Stevens et al., above, with a stainless steel central portion as taught by Radisch, Jr. in order to provide a core wire of a suitably strong material that can be formed and maintained in a desired shape.

5. **Claims 28, 35, 38-39, 45 & 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. ('349) in view of Radisch, Jr. ('493), Stevens et al. ('803), Chaisson et al. ('548), and further in view of Ferrera (US 6,165,140).

Rodriguez et al. as modified by Radisch, Jr., Stevens et al. and Chaisson et al. disclose a guide wire, as described above, that fails to explicitly teach a radiopaque guide wire or a polytetrafluoroethylene coated wire coil.

However, **Ferrera** discloses a guide wire comprising a radiopaque guide wire and a wire coil having a portion 40 coated with polytetrafluoroethylene (PTFE) (see col. 3, lines 42-48).

In regards to **claims 28, 39 & 47**, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr., Stevens et al. and Chaisson et al. with a radiopaque coil as taught by Ferrera in order to increase the visibility of the guide wire under fluoroscopy.

In regards to **claims 35, 38 & 45**, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr., Stevens et al. and Chaisson et al. with a PTFE coating as taught by Ferrera in order to improve the lubricity of the guide wire and fixedly maintain the wire coil in place.

6. **Claims 7 & 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. ('349) in view of Radisch, Jr. ('493), Stevens et al. ('803), Chaisson et al. ('548), and further in view of Clayman et al. (US 6,716,183).

Rodriguez et al. as modified by Radisch, Jr., Stevens et al. and Chaisson et al. disclose a guide wire, as described above, that fails to explicitly teach coils that are laser welded to the mandrel portion.

However, **Clayman et al.** disclose(s) a guide wire to assist in anatomic deployment, the guide wire having: an elongate central zone 18 of high stiffness, and substantially constant diameter along its length; a proximal zone 21 of transition from high stiffness to semi-stiffness and having a length; and a tapered segmental distal zone 16 of transition from high stiffness to being relatively flexible; wherein the proximal

zone 21 comprises a tapered mandrel with a proximal wire coil 41 of substantially constant coil diameter on and extending along the tapered mandrel; wherein the proximal wire coil is laser welded to the tapered mandrel (see fig. 7; column 6/lines 45-48); wherein the proximal wire coil terminates in a rounded tip 50 (see fig. 2).

Since Rodriguez et al. teach a wire coil that is epoxied (i.e. semi-permanent attachment) or soldered (i.e. permanent attachment) in order to attach the wire coil to the shaft (see col. 3, lines 45-46), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the guide wire of Rodriguez et al. as modified by Radisch, Jr., Stevens et al. and Chaisson et al. with laser welded wire coil as taught by Clayman et al. in order to permanently attach the wire coil to the shaft.

Response to Arguments

7. Applicant's arguments filed March 31, 2008 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. T./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736